

REMARKS

FORMAL MATTERS:

Claims 1, 3, 6, 8-16, 18, 21, 23-35 are pending in the application after entry of the amendments set forth herein.

Claim 36 is canceled without prejudice.

Claims 1, 16, and 31 have been amended. Support for these amendments is found throughout the specification, e.g., at page 20, lines 25-27.

No new matter has been added.

REJECTIONS UNDER 35 U.S.C. § 112 FIRST PARAGRAPH

Claims 1, 3, 6, 8-16, 18, 21 and 23-36 are rejected under 35 U.S.C. §112, first paragraph as allegedly failing to comply with the written description requirement.

In making this rejection, the Examiner asserts that the instant application claims subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner asserts that Claims 1, 3, 6, 8-16, 18, 21 and 23-36 do not comply with the written description requirement because the specification allegedly does not support the limitation that “the polymer providing the hydrophilic domains is present in an amount from 0.01-2%”. (see Office Action dated August 16, 2010 at page 2)

In the spirit of expediting prosecution and without conceding to the correctness of the rejection, Claims 1, 16 and 31 have been amended to specify that “the amount of the polymer in the conductive ink is about 1% by weight”. Applicants submit that the claims, as amended sufficiently comply with the written description requirement. Indeed, the Examiner acknowledges that the specification supports the limitation where the percentage of polymer in the conductive ink is about 1%. (see Office Action dated August 16, 2010 at page 2 and in the specification at page 20, lines 25-27)

With respect to Claims 35 and 36, the Examiner asserts that “the original filed disclosure also never explicitly set forth an electrode having less polymer than enzyme” and that “[t]here

are no explicit example of a conductive ink containing a non-zero amount of polymer where there is less than enzyme”.

Applicants respectfully disagree with the assertions of the Examiner and submit that the element of “wherein the amount of enzyme is greater than the amount of polymer in the conductive ink” is fully supported by the specification and thus, sufficiently complies with the written description requirement.

The law is clear that in order to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail *that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention*. See e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 U.S.P.Q.2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991) (*emphasis added*).

Indeed, as stated in M.P.E.P §2163.02, the standard for determining compliance with the written description requirement is whether “the description clearly allows persons of skill in the art to **recognize** that [applicant] invented what is claimed” See *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1991)(*emphasis added*). .

As discussed above and acknowledged by the Examiner, the specification fully supports that the amount of polymer in the conductive ink may be about 1% by weight. In making this rejection, the Examiner asserts that the specification only discloses that “the enzyme was typically present in amounts from 0-1% by weight” (see Office Action dated August 16, 2011 at page 3) and concludes that the specification allegedly does not support the limitation of “wherein the amount of enzyme is greater than the amount of polymer in the conductive ink”. However, contrary to the assertions of the Examiner, Table 1 discloses that the amount of enzyme in the conductive ink may range from 0 to 2% by weight. For example, Biosensor III summarized in Table 1 on page 12 of the specification clearly shows that the enzyme may range from 0.1-2% by weight in the working electrode, conductive track and electrical contact. As such, Applicants submit that based on this disclosure alone, one of ordinary skill in the art would reasonably recognize that the specification fully describes the element of “wherein the amount of enzyme is greater than the amount of polymer in the conductive ink”. For example, one of ordinary skill in the art would understand that one possible biosensor may include the enzyme in an amount of

about 2% by weight and an amount of polymer of about 1% by weight. Therefore, Applicants submit that the element of “wherein the amount of enzyme is greater than the amount of polymer in the conductive ink” is fully supported by the specification, and thus sufficiently complies with the written description requirement.

Accordingly, in view of the amendments to the claims and the remarks made above, the Applicants respectfully request that the rejection of Claims 1, 3, 6, 8-16, 18, 21 and 23-36 under 35 U.S.C. §112, first paragraph, be withdrawn.

REJECTIONS UNDER 35 U.S.C. §103(A)

Claims 1, 3, 6, 8-11, 29, 31, 35, and 36 – Say, Charlton, Maley, Hoenes and Ikeda

Claims 1, 3, 6, 8-11, 29, 31, 35, and 36 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Say et al. (US Patent No. 6,103,033) in view of any one or more of Charlton et al. (US Patent No. 5,798,031), Maley et al. (US Patent No. 5,770,028) and/or Hoenes et al. (US Patent No. 5,122,244) with evidence from Ikeda (US Patent No. 5,582,697).

In making the rejection, the Examiner asserts that Say teaches all of the claimed limitations apart from the element of “a polymer that provides a hydrophilic domain”. (Office Action dated August 16, 2010 at page 4) To remedy this deficiency, the Examiner cites Charlton for its alleged teaching that “the enzyme can be deposited down onto an electrode in presence of a hydrophilic polymer, which would increase hydration access to the enzyme itself”, asserting that “[i]t would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Charlton for the sensor of Say so as to increase the hydration properties of the electrode thereby permit adequate sample exposure to the enzyme. To further support the Examiner’s assertions, the Examiner cites Hoenes for its alleged teaching of an electrode that contains “a small amount of hydroxyethyl cellulose, which is a polymer having hydrophilic domains”, Maley for its alleged teaching that “it is desirable to add a surfactant material to the electrode in order to facilitate wetting of the electrode”, and Ikeda for its alleged teaching that “a given reference electrode for the sensor can be utilized as a trigger electrode as well” (see Office Action dated August 16, 2010 at pages 4-6).

In order to meet its burden in establishing a rejection under 35 U.S.C. § 103(a), the Office must first demonstrate that the combined prior art references teach or suggest all the claimed limitations. See *Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342 (Fed. Cir. 2007) (“the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make [every element of] the composition or device, or carry out the [entire] claimed process, and would have had a reasonable expectation of success in doing so,” (citing *KSR Int’l Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1395 (U.S. 2007))).

An element of the claimed invention is “the amount of the polymer in the conductive ink is about 1% by weight”. As such, the conductive ink comprises about 1% by weight a polymer that provides hydrophilic domains in the conductive ink. Applicants submit that none of the cited references teach or suggest this element of the claims. Indeed, Say, Charlton, Hoenes Maley and Ikeda are completely silent to a polymer in the conductive ink in an amount of about 1% by weight. Specifically, with respect to Charlton, it remains the Applicant’s position (as discussed in detail in the Response to Office Actions filed February 8, 2010 and August 19, 2008 and in the Appeal Brief filed November 7, 2008) that Charlton does not teach incorporation of the hydrophilic polymer in the conductive ink of the working electrode in the manner disclosed by the claimed invention. For the sake of brevity, the Applicants’ prior arguments are not reiterated herein.

In making the rejection, the Examiner asserts that Hoenes teaches this claim element asserting that Hoanes “appears to teach that only a small amount of hydrophilic polymer is necessary for inducing the desired hydrophilic domains for the electrode”. To support this assertion, the Examiner cites Hoenes at Col. 19, lines 17-27 and concludes that “[i]t would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize less than 2% of the polyethylene glycol or surfactant of Charlton or Maley as suggested by Hoenes because only a small amount of hydrophilic material is necessary for improving the sensor wetting properties”. (see Office Action dated August 16, 2010 at page 5)

Applicants respectfully disagree with the assertions of the Examiner and submit that Hoenes, including the passage cited by the Examiner, fails to teach or suggest the element of a polymer for providing hydrophilic domains in the conductive ink in an amount of about 1% by

weight, as required by the rejected claims. Indeed, Applicants have carefully reviewed Hoenes and find no mention or suggestion of including a polymer in the conductive ink in an amount of about 1% by weight. To the contrary, Hoenes specifically discloses in the passage cited by the Examiner, that the working electrode comprises “**4% by weight** ethylene glycol”. (emphasis added). Therefore, contrary to the assertions of the Examiner, Hoenes fails to teach or suggest the element of “the amount of the polymer in the conductive ink is about 1% by weight”, as claimed. As such, Applicants submit that none of the cited references teach or suggest that “the amount of the polymer in the conductive ink is about 1% by weight”, as required by the rejected claims.

With respect to Claim 35, in making the rejection, the Examiner asserts that the combination of Say, Charlton, Maley, Hoenes and Ikeda teaches all of the claimed limitations.

However, an element of the claimed invention is “wherein the amount of enzyme is greater than the amount of polymer in the conductive ink”. Applicants submit that none of the cited references teach or suggest this element of the claims. Indeed, Say, Charlton, Hoenes, Maley and Ikeda are completely silent to an enzyme in the conductive ink in an amount that is greater than the amount of polymer in the conductive ink”.

In making the rejection, the Examiner asserts that Hoenes teaches this claim element because Hoenes “teaches that only a small percentage of hydrophilic polymer is necessary for successful wetup” and therefore concludes that “it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize an amount of polymer of Charlton or Maley less than the amount of enzyme because very little polymer appears to be necessary for successful wetup”. (see Office Action dated August 16, 2010 at pages 6-7)

Applicants respectfully disagree with the Examiner’s characterization of the teachings of the cited references and submit that Hoenes fails to teach or suggest that the amount of enzyme is greater than the amount of polymer in the conductive ink, as is claimed. Indeed, Hoenes is completely silent to an enzyme in the conductive ink in an amount greater than the amount of polymer in the conductive ink. At best, the cited passage of Hoenes discloses that the amount of polymer required in the working electrode is at least “**4% by weight** ethylene glycol”. Contrary to the assertions of the Examiner, Hoenes neither teaches nor suggests that the amount of enzyme

is greater than the amount of polymer in the conductive ink. Merely asserting that “very little polymer appears to be necessary for successful electrode wetup” is not the same as requiring that the amount of enzyme be greater than the amount of polymer in the conductive ink. There is nothing in the Hoenes reference to suggest that the disclosed amount of polymer necessarily means that “the amount of enzyme is greater than the amount of polymer in the conductive ink”, as is required by the rejected claim. In fact, Hoenes never discloses or suggests that only “very little polymer” is necessary for electrode wetup. Hoenes only discloses that the working electrode included “4% by weight ethylene glycol”.

As such, because all of the cited references either alone or in combination, fail teach the elements of “the amount of the polymer in the conductive ink is about 1% by weight” and “the amount of enzyme is greater than the amount of polymer in the conductive ink”, as claimed, these references fail to teach or suggest each and every element of the rejected claims and therefore a *prima facie* case of obviousness cannot be established. Applicants thus, respectfully request withdrawal of this rejection.

Claims 1, 3, 6, 8-16, 18, 21, 23-31, 35 and 36 – Feldman, Say, Charlton, Maley, Hoenes and Ikeda

Claims 1, 3, 6, 8-16, 18, 21, 23-31, 35 and 36 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Feldman in view of Say and any of Charlton, Maley, and/or Hoenes and with evidence from Ikeda.

As discussed above, elements of the claimed invention are “the amount of the polymer in the conductive ink is about 1% by weight” and “the amount of enzyme is greater than the amount of polymer in the conductive ink”. The Applicants submit that none of the cited references alone or in any combination teach or suggest these elements of the claims.

Since Feldman does not teach or suggest preparing an electrode by incorporating a hydrophilic polymer in the conductive ink, Feldman cannot remedy the deficiencies of Say, Charlton, Maley, Hoenes and Ikeda. Applicants thus, respectfully request withdrawal of this rejection.

Claims 32 and 34 – Say, Charlton, Maley, or Hoenes and Yamashita

Claims 32 and 34 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Say in view of any of Charlton, Maley, or Hoenes and in further view of Yamashita (US Patent No. 5,472,590).

As discussed in detail above, the combination of Say, Charlton, Maley and Hoenes fails to render the claimed invention obvious. As Yamashita has merely been cited for its alleged teaching of polyethylene glycol as a type of hydrophilic polymer, Yamashita fails to remedy the deficiencies of Say, Charlton, Maley and Hoenes.

Applicants thus, respectfully request withdrawal of this rejection.

Claims 32-34- Feldman, Say, Charlton, Maley, Hoenes and Yamashita

Claims 32-34 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Feldman in view of Say and Charlton, and in further view of Yamashita.

As discussed above, the combination of Feldman, Say, Charlton, Maley and Hoenes fails to render the claimed invention obvious. As Yamashita has merely been cited for its alleged teaching of polyethylene glycol as a type of hydrophilic polymer, Yamashita fails to remedy the deficiencies of Feldman, Say and Charlton.

Applicants thus, respectfully request withdrawal of this rejection.

CONCLUSION

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Office finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, reference number ADCI-073.

Respectfully submitted,
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